§ 460.122 Clindamycin concentrated stock solutions for use in antimicrobial susceptibility test panels.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Clindamycin concentrated stock solutions for use in preparing susceptibility test panels are frozen aqueous clindamycin hydrochloride stock solutions serially diluted with distilled water to contain approximately the following concentrations: 640, 320, 160, 80, 40, 20, and 10 micrograms of clindamycin per milliliter. The potency of each diluted solution is satisfactory if it is not less than 90 percent and not more than 140 percent of the number of micrograms of clindamycin that it is represented to contain. The pH of the solution containing 640 micrograms of clindamycin per milliliter is not less than 4.5 and not more than 7.0. The clindamycin used conforms to the standards prescribed by § 453.20(a)(1) (i), (ii), (iv), (v), (vi) and (vii) of this chapter.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for potency and pH.

(ii) Samples required: A minimum of five frozen aliquots of each dilution of the concentrated stock solutions, each containing at least 5 milliliters.

(b) *Tests and methods of assay.* The sample solutions must be thawed and brought to room temperature before testing.

(1) *Potency.* Proceed as directed in § 436.105 of this chapter. Prepare the sample for assay by diluting an accurately measured representative portion of the sample with 0.1*M* potassium phosphate buffer, pH 8.0 (solution 3), to the reference concentration of 1.0 microgram of clindamycin per milliliter (estimated).

(2) *pH.* Proceed as directed in § 436.202 of this chapter, using the solution containing 640 micrograms of clindamycin per milliliter.

§ 460.125 Colistin concentrated stock solution for use in antimicrobial susceptibility test panels.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Colistin concentrated stock solutions for use in preparing antimicrobial susceptibility test panels are frozen aqueous colistin sulfate stock solutions serially diluted with distilled water to contain an approximate concentration of 160 micrograms of colistin per milliliter. Its potency is satisfactory if it is not less than 90 percent and not more than 140 percent of the number of micrograms of colistin that it is represented to contain. Its pH is not less than 5.0 and not more than 8.0. The colistin used conforms to the requirements of § 448.21(a)(1) (i), (iii), (iv), and (v) of this chapter.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for potency and pH.

(ii) Samples required: Five frozen aliquots of the concentrated stock solution containing at least 5 milliliters.

(b) *Tests and methods of assay.* The sample solution must be thawed and brought to room temperature before testing.

(1) *Potency.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Dilute an accurately measured representative portion of the sample with 10 percent potassium phosphate buffer (solution 6), to the reference concentration of 1.0 microgram of colistin per milliliter (estimated).

(2) *pH.* Proceed as directed in § 436.202 of this chapter, using the solution without further dilution.

§ 460.128 Erythromycin concentrated stock solutions for use in antimicrobial susceptibility test panels.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Erythromycin concentrated stock solutions for use in preparing antimicrobial susceptibility test panels are frozen aqueous erythromycin stock